NEW YORK INSTITUTE OF TECHNOLOGY

OFFICE OF SPONSORED PROGRAMS AND RESEARCH

Cayuse Human Ethics IRB Protocol Submission System Directions for NYIT Employees and Students to Submit a New IRB Application

NYIT has adopted the CAYUSE module for the submission and review of Institutional Review Board (IRB) Protocols. At this time, we are only accepting **NEW** submissions. It is your responsibility as a faculty member, student, or staff member to comply with the IRB protocol that is submitted. If you have a modification, renewal, or termination on a **previous protocol**, please contact <u>grants@nyit.edu</u>

Information on Human Ethics and IRB can be found on the NYIT website: <u>nyit.edu/ospar/institutional_review_board</u>

What is Cayuse?

The Cayuse Research Suite is NYIT's system to support the submission of grant proposals to external sponsors, Award Process, IRB Protocols to the NYIT ESB or BHS IRB and Disclosure of Outside Interests and it helps to allow NYIT maintain compliance with the rules and regulations governing these items.

First time accessing Cayuse as an NYIT Employee or Student?

NYIT employees or students can access Cayuse through this URL: <u>nvit.app.cayuse.com/</u> If you try to log in and see an error message that you are unable to access the site, email <u>cayusesupport@nvit.edu</u> or <u>grants@nvit.edu</u>mailto:grants@nyit.edu

First time accessing Cayuse as a Guest:

Guests can access Cayuse through this URL: nvit.app.cayuse.com/guest

Make sure you coordinate with the NYIT Office of Sponsored Projects and Research so that they can add you as a guest user to the CAYUSE system. If you are a guest and cannot access the system, please contact cayusesupport@nyit.edu or grants@nyit.edu to grants@nyit.edu be added to the system.

Who is eligible to be a Principal Investigator?

Students are not eligible to be principal investigators on their submission and will need a faculty sponsor. See further detail here: (include new policy here – Eileen and Jared may post this to Grants website)

Items needed prior to submitting:

- 1) Required CITI training:
 - Complete the appropriate training in CITI for all Investigators.
 - Go to <u>citiprogram.org http://www.citiprogram.org/</u>to register and complete the required courses listed under Human Subjects Research
 - Most students and faculty will need either:
 - Group 1: Biomedical Researchers and Key Personnel; or
 - Group 2: Social-Behavioral-Educational (SBE) Researchers and Key Personnel
 - For more information, please see our website at <u>nyit.edu/ospar/institutional_review_board</u> <u>https://www.nyit.edu/ospar/institutional_review_board</u>for training on how complete the required IRB, FAQs, and new learner registration information.
 - <u>https://www.nyit.edu/ospar/institutional_review_board</u> Completed certificates will be synched with the Cayuse system.
- 2) Get Site/Permission Letters if Applicable: If research is to be conducted off-site, a permission letter from the site on their letterhead is required to be uploaded.
- **3)** Attach all surveys, forms, interview questions, etc., in final form: NYIT-approved survey platforms are REDCAP (HIPAA information) or Qualtrics.
 - Examples of informed consent survey headers and disclaimers templates can be found on our website at: <u>nyit.edu/ospar/institutional_review_board</u>
- 4) Attach all recruitment material and flyers (if applicable)

- 5) Attach informed consent documents: Modify the sample consent templates at <u>nyit.edu/ospar/institutional review board</u>
 - Key information is located at the top of the page, and in easily understood language at the 8th grade reading level.
 - Use <u>webfx.com/tools/read-able</u>/ to ensure all elements are listed clearly at the appropriate reading level (according to <u>46.116</u>)
 - A statement that the study involves research
 - An explanation of the purposes of the research
 - The expected duration of the subject's participation
 - A description of the procedures to be followed
 - Identification of any procedures which are experimental
 - A description of any reasonably foreseeable risks or discomforts to the subject
 - A description of any benefits to the subject or to others which may reasonably be expected from the research
 - A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
 - A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
 - For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
 - Research, Rights or Injury: An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
 - A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

Additional Elements as Appropriate

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- Any additional costs to the subject that may result from participation in the research
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
- The approximate number of subjects involved in the study
- 6) Chair departmental signature needed for submission, complete here: <u>https://web.nyit.edu/files/academic_affairs/AA_OSPAR_DepartmentChairApproval.pdf</u>

Submission Process through Cayuse

1) Submitting an IRB protocol through the CAYUSE Human Ethics Module:

- If you are an internal NYIT employee and would like to submit an IRB protocol you can do so by going to https://nyit.cayuse.com.
- This will then redirect you to the Okta Single Sign On page where you would use your NYIT Okta ID and password to log in to the system.
- If you need assistance contact <u>cayusesupport@nyit.edu</u>

2) Once you are logged into the CAYUSE system

a) You will see this screen

Security Cayuse platform Home				° 🔝 :	Products * 🛔 OSPAR Account
		My Tasks			+ New Task
			Assi	gned to Me Created by Me	Open All
Tasis @	Tosk Type	From Assigned To	Created \$	Last Activity	Due - Status
		No Saved Tasks			
)
					97

b) Click on the "Products" drop-down menu on the top right-hand side and select "Human Ethics"

caguse platform Home						🖲 💽 Products 🔹	GSPAR Account
My Tasks							New Task
					Assigned to Me Create	Human Ethics	-IIA firms
Task #	Task Type	From	Assigned To	Created \$	Last Activity	Due -	Status
		No Saved Tosks					

3?

c)	Click "+	New Study",	which	will br	ring y	you to	this	page
----	----------	-------------	-------	---------	--------	--------	------	------

cayuse Human Ethi	CS							Products 💌	🛔 OSPAR Account 🔻
board Studie	s Submissions Task	ks							
es / Study Details									+ New Submission
		Study Details				Submissions			
Enter study title he	re								
armed Data:	Evaluation Date:	Ormolystica	A stiller						
niovai baoe. A min ©heck-In Date:	N/A Closed Date:	N/A Current Policy	Submissions: Sponsors:						
A	N/A	,	N/A						
									%
	Cayuse Human Ethi board Stude 2: 5 Study Details Enter study tilde he 2: PDF © De proval Date: A nin Check in Date:	Caguse Human Ethics board Studies Submissions Tas s Study Details Enter study title here proval Date: Expiration Date: A N/A min Check in Date: Closed Date: A N/A	Caguse Human Ethics board Studies Submissions Tasks 2 Study Details Enter study title here POP Coefficient A NA NA NA NA NA	Caguse Human Ethics board Studies Submissions Tasks I Study Details I Inter study title here Pror Coefficient Coefficient Pror Coefficient Coe	Cayuse Human Ethics board Studies Submissions Tests Study Details Enter study title here POF Connect proval Date: Expiration Date: Organization: Active A NIA NIA Submissione: min Check in Date: Corrent Policy Sponsor: A NIA NIA NIA	Capuse Human Ethics Doard Studie Submissions Tasks Study Details Enter study title hare POF Details proval Date: Expiration Date: Organization: Active A NA NA NA Submissione: Submissione: NA NA Submissione: NA NA NA NA Submissione: NA	Services Human Ethics Soord Studies Submissions Taks Sobrid Studies Submissions Studies Submissions Su	Explore Image: Comparison of Studies Takes a study Obtails Study Details Study Study Obtails Study Obtails a study Obtails Study Obtails Study Obtails Study Obtails a study Obtails Study Obtails Study Obtails Study Obtails a study Obtails Study Obtails Study Obtails Study Obtails	Studie Studies Studies Taks Concern Studies St

- d) Enter the Study Title that you would like to use.
- e) Click the blue check mark to the right under the title, which will bring you to this next page

Studies / Study Details						+ New Submission		
		Study Details			Submissions			
Unsubmitted								
NYIT IRB-2023-26 T	his is a test							
Approval Date: N/A Admin Check-In Date: N/A	Expiration Date: N/A Closed Date: N/A	Organization: Current Policy Post-2018 Rule	Active Submissions: N/A Sponsors: N/A	Population Flags:	Additional Flags:			
Key Contacts① Attachm Team Member	ients Flags		Role	Number	Email			
No Key Study Contacts.								

- f) Please click on the blue button for "+New Submission" in the upper right-hand corner.
- g) You are now ready to begin your submission! Complete each section of the IRB application in Cayuse. Be sure to include all procedures in detail and written in a way that all reviewers can understand. Be sure the purpose is clear and that all steps in the procedure are clearly listed. Cayuse uses branch logic, so as you complete a section, a new section may appear.
- h) Choose the Appropriate Level of IRB review: Exempt, Expedited, or Full Board (see more information here: https://www.nyit.edu/ospar/institutional_review_board)

Completing your Submission

The **Complete Submission** button will only appear when you have check marks next to all of your sections. If one of your sections doesn't have a check mark and you aren't sure why, click on the section to search for any required questions you may have missed.

Once you have filled out every section of your submission and have added all required attachments, a **Complete Submission** option appears beneath **Routing** within the menu. After clicking Complete Submission, you will be prompted to **Confirm** or **Cancel**.

1) Certification

Your completed submission is sent to the PI for certification. The PI will receive an email letting them know that the submission needs to be certified. When the PI certifies the submission, they are asserting the submission is complete and accurate and are accepting their PI responsibilities.

If the PI decides that changes need to be made, they will send the submission back. All research team members will receive an email notifying them of the change in status so they can make the necessary edits and complete the submission once more.

Once the PI has certified the submission, the submission will be reviewed by the organizational approver and routed to the Analyst. The submission may be returned at any point for edits or clarification. **Please note:** If your institution does not have an approver, the submission may be routed directly to the Analyst.

Completing Submission as a PI: If you are a PI completing your submission, you should be able to then certify the submission right away.

Co-PIs: Your institution's settings may require that any Co-PIs on the study also certify the submission. These individuals also have the ability to return to the submission to the research team.

Recertification: If the submission does get returned to the research team, all previous certifications are cleared. All individuals who were required to certify the submission in previous rounds of routing must recertify every time the submission is returned before it can move forward.

After submission is completed:

- Be sure to **Save** the Cayuse Application itself within the submission, **Certify** the information is correct, and **Submit**.
 - All PIs and Co-PIs must certify the application.
 - Download the <u>Chair Approval Letter</u>, have your departmental Chair sign, and PI to upload into the Cayuse system.
 - Your application will then be routed to the IRB analyst to start the process.
- Wait for Review Correspondence or Approval Letter. If your submission is returned, review each comment and make comments and changes and **Re-Save, Certify and Submit**.
- Once you receive your letter of approval you may begin your research.
- Any changes to your approved IRB must be approved via Modification to your submission in Cayuse.
 - Log in and select the approved IRB to modify the initial submission and request approval.

If you have any questions, please contact Eileen Gazzola at <u>egazzola@nyit.edu</u> or <u>grants@nyit.edu</u>